

Bard Medical Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30209-2695

MAY 14 2004

K040504
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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name:	C. R. Bard, Inc., Medical Division
Address:	8195 Industrial Blvd. Covington, GA 30014
Contact Person:	John C. Knorpp
Contact Person's Telephone Number:	770-784-6451
Contact Person's Fax:	770-784-6419
Date of Preparation:	February 24, 2004

B. DEVICE NAME:

Trade Names:	Bardex® All-Silicone Foley Catheter Lubri-Sil® All-Silicone Foley Catheter Lubri-Sil® I.C. All-Silicone Foley Catheter
Common / Usual Name:	Foley Catheter
Classification Names:	Catheter, Retention Type, Balloon Catheter, Urological (Antimicrobial) and Accessories 21 CFR 876.5130

C. PREDICATE DEVICE NAME:

Trade Names:	Bardex® All-Silicone Foley Catheter Lubri-Sil® All-Silicone Foley Catheter Lubri-Sil® All-Silicone I.C. Foley Catheter
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D. DEVICE DESCRIPTION:

The Bard® all-silicone Foley catheter is a two-way all silicone Foley catheter which is placed in the bladder through the urethra. The balloon on the distal end of the catheter is inflated with sterile water after insertion and used to secure the catheter in place and ensure that the opening in the distal tip of the catheter is positioned correctly to allow for urine drainage. The urine drains out through the catheter into a collection device attached to the catheter.

E. INTENDED USE:

The Bardex®, Lubri-Sil® and Lubri-Sil® IC All-Silicone Foley Catheters are intended for use in the drainage and/or collection and/or measurement of urine.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The Bardex®, Lubri-Sil® and Lubri-Sil® IC All-Silicone Foley Catheters are constructed of healthcare grade silicone. They have the same intended use, general design and fundamental scientific technology as the predicate devices.

G. PERFORMANCE DATA SUMMARY:

The Bardex®, Lubri-Sil® and Lubri-Sil® IC All-Silicone Foley Catheters were tested in accordance with the relevant standards for function and biocompatibility.



MAY 14 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John C. Knorpp
Sr. Regulatory Affairs Specialist
Bard Medical Division
C. R. Bard, Inc.
8195 Industrial Blvd.
COVINGTON GA 30209-2695

Re: K040504

Trade/Device Name: Bardex[®], Lubri-Sil[®] and Lubri-Sil[®] I.C. All-Silicone Foley Catheters
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 EZL
Dated: February 24, 2004
Received: February 27, 2004

Dear Mr. Knorpp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

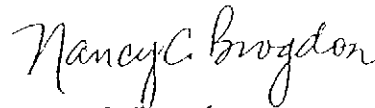
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1.3 Indications for Use Statement

510(k) Number (if known): K040504

Device Name: Bardex®, Lubri-Sil® and Lubri-Sil® I.C. All-Silicone Foley Catheters

Indications for Use:

The Bardex®, Lubri-Sil® and Lubri-Sil® I.C. All-Silicone Foley Catheters are indicated for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as nephrostomy tract.

(PLEASE DO NOT WRITE BELOW THIS LINE --
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1/2/96)

David R. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040504